IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : John David Fraser et al Art Unit :
Serial No. : Examiner :
Filed : December 4, 2001
Title : IMMUNOMODULATORY CONSTRUCTS AND THEIR USES

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the specification:

Insert the following paragraph beginning page 1, paragraph 1:

-- This application claims priority from U. S. Provisional Application Serial no. 60/251,243 filed December 4, 2000 and PCT application filed in Australia, December 3, 2001 (serial number not available).

In the claims:

Cancel claims 19 and 20.

Claims 3-5, 8-17, 23-25, 30, 36-38 have been amended as follows:

-- 3. (Amended) An immunomodulator according to claim 1, wherein the T-cell receptor binding site, or at least a part thereof, of the antigen-presenting- cell (APC) targeting molecule has been modified by substitution or addition.

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4. (Amended) An immunomodulator according to claim 1, wherein the T-cell binding site of the antigen-presenting cell (APC) targeting molecule has been deleted.

5. (Amended) An immunomodulator according to claim 1, wherein the antigen-presenting cell (APC) targeting molecule is derived from *Staphylococcus aureus* and/or *Streptococcus pyogenes*.

8. (Amended) An immunomodulator according to claim 6, wherein the antigen-presenting cell (APC) targeting molecule is designated SPEC-Y15A R181Q.

9. (Amended) An immunomodulator according to claim 6, wherein the antigen-presenting cell (APC) targeting molecule is designated SPEC-Y15A.C27S.N79C.R181Q.

10. (Amended) An immunomodulator according to claim 1, wherein the antigen-presenting- cell (APC) targeting molecule is coupled reversibly to an immunomodulatory antigen.

11. (Amended) An immunomodulator according to claim 1, wherein the immunomodulatory antigen is a protein, a polypeptide and/or a peptide.

12. (Amended) An immunomodulator according to claim 1, wherein the immunomodulatory antigen is a nucleic acid.

13. (Amended) An immunomodulator according to claim 1, wherein the immunomodulatory antigen is non-immunogenic when not coupled to the antigen-presenting cell (APC) targeting molecule.

14. (Amended) An immunomodulator according to claim 4, wherein the antigen-presenting cell (APC) targeting molecule is SPEC (-20-90).

15. (Amended) Pharmaceutical composition comprising an immunomodulator according to claim 1 and a pharmaceutically acceptable carrier, adjuvant, excipient and/or solvent.

16. (Amended) Vaccine comprising an immunomodulator according to claim 1.

17. (Amended) Method of therapeutic or prophylactic treatment of a disorder which requires the induction or stimulation of the immune system, comprising the administration to a subject requiring such treatment of an immunomodulator according to claim 1.

23. (Amended) A method according to claim 21, wherein the antigen-presenting cell (APC) targeting molecule is SPE-C Y15A R181Q.

24. (Amended) A method according to claim 21, wherein the antigen-presenting cell (APC) targeting molecule is designated SPEC-Y15A.C27S.N79C.R181Q.

25. (Amended) A method according to claim 21, wherein the antigen-presenting cell (APC) targeting molecule is SPEC (-20-90).

30. (Amended) A method according to claim 26, wherein the antigen-presenting cell (APC) targeting molecule is derived from *Staphylococcus aureus* and/or *Streptococcus pyogenes*.

36. (Amended) A method according to claim 26, wherein the antigen-presenting- cell (APC) targeting molecule is coupled reversibly to said compound.

37. (Amended) A method according to claim 26, wherein the compound is selected from the group consisting of a protein, a polypeptide and/or a peptide, a carbohydrate or a nucleic acid.

38. (Amended) A method according to claim 26, wherein the compound is non-immunogenic when not coupled to the antigen-presenting cell (APC) targeting molecule. --

REMARKS

Applicants have amended the dependency of the claims to preclude a rejection under 35 U.S.C. § 112, fifth paragraph, which provides in part that "[a] multiple dependent claim shall not serve as a basis for any other multiple dependent claim." No new matter has been added by the above amendment.

Attached is a marked-up version of the changes being made by the current amendment.

Claims 1-18 and 21-38 are now pending. Prompt examination of the present application, as amended, is respectfully requested. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 12-4-01

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Version with markings to show changes made

In the claims:

Claims 19 and 20 have been cancelled.

Claims 3-5, 8-17, 23-25, 30, 36-38 have been amended as follows:

3. (Amended) An immunomodulator according to claim 1 [or claim 2], wherein the T-cell receptor binding site, or at least a part thereof, of the antigen-presenting- cell (APC) targeting molecule has been modified by substitution or addition.

4. (Amended) An immunomodulator according to claim 1 [or claim 2], wherein the T-cell binding site of the antigen-presenting cell (APC) targeting molecule has been deleted.

5. (Amended) An immunomodulator according to [any one of claims 1 to 3] claim 1, wherein the antigen-presenting cell (APC) targeting molecule is derived from *Staphylococcus aureus* and/or *Streptococcus pyogenes*.

8. (Amended) An immunomodulator according to claim 6 [or claim 7], wherein the antigen-presenting cell (APC) targeting molecule is designated SPEC-Y15A R181Q.

9. (Amended) An immunomodulator according to [any one of claims 6 to 8] claim 6, wherein the antigen-presenting cell (APC) targeting molecule is designated SPEC-Y15A.C27S.N79C.R181Q.

10. (Amended) An immunomodulator according to [any one of claims 1 to 9] claim 1, wherein the antigen-presenting- cell (APC) targeting molecule is coupled reversibly to an immunomodulatory antigen.

11. (Amended) An immunomodulator according to [any one of claims 1 to 10] claim 1, wherein the immunomodulatory antigen is a protein, a polypeptide and/or a peptide.

12. (Amended) An immunomodulator according to [any one of claims 1 to 10] claim 1, wherein the immunomodulatory antigen is a nucleic acid.

13. (Amended) An immunomodulator according to [any one of claims 1 to 12] claim 1, wherein the immunomodulatory antigen is non-immunogenic when not coupled to the antigen-presenting cell (APC) targeting molecule.

14. (Amended) An immunomodulator according to [claim any one of claims 4 or 10 to 13] claim 4, wherein the antigen-presenting cell (APC) targeting molecule is SPEC (-20-90).

15. (Amended) Pharmaceutical composition comprising an immunomodulator according to [any one of claims 1 to 14] claim 1 and a pharmaceutically acceptable carrier, adjuvant, excipient and/or solvent.

16. (Amended) Vaccine comprising an immunomodulator according to [any one of claims 1 to 14] claim 1.

17. (Amended) Method of therapeutic or prophylactic treatment of a disorder which requires the induction or stimulation of the immune system, comprising the administration to a subject requiring such treatment of an immunomodulator according to [any one of claims 1 to 14, of a pharmaceutical composition according to claim 15 or of a vaccine according to claim 16] claim 1.

19. (Cancelled) Use of an immunomodulator according to any one of claims 1 to 14 for the preparation of a medicament for the therapeutic or prophylactic treatment of a disorder which requires the induction or stimulation of the immune system.

20. (Cancelled) Use according to claim 19, wherein the disorder is selected from the group consisting of bacterial, viral, fungal or parasitic infection, autoimmunity, allergy and/or pre-neoplastic or neoplastic transformation.

23. (Amended) A method according to claim 21 [or claim 22], wherein the antigen-presenting cell (APC) targeting molecule is SPE-C Y15A R181Q.

24. (Amended) A method according to [any one of claims 21 to 23] claim 21, wherein the antigen-presenting cell (APC) targeting molecule is designated SPEC-Y15A.C27S.N79C.R181Q.

25. (Amended) A method according to claim 21 [or claim 22], wherein the antigen-presenting cell (APC) targeting molecule is SPEC (-20-90).

30. (Amended) A method according to [any one of claims 26 to 29] claim 26, wherein the antigen-presenting cell (APC) targeting molecule is derived from *Staphylococcus aureus* and/or *Streptococcus pyogenes*.

36. (Amended) A method according to [any one of claims 26 to 29] claim 26, wherein the antigen-presenting- cell (APC) targeting molecule is coupled reversibly to said compound.

37. (Amended) A method according to [any one of claims 26 to 29] claim 26, wherein the compound is selected from the group consisting of a protein, a polypeptide and/or a peptide, a carbohydrate or a nucleic acid.

38. (Amended) A method according to [any one of claims 26 to 29] claim 26, wherein the compound is non-immunogenic when not coupled to the antigen-presenting cell (APC) targeting molecule.